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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods Biennial Progress Report: 2020-2021; Availability of Report

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces availability of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Biennial Progress Report: 2020-2021. This report, prepared in accordance with requirements of the ICCVAM Authorization Act of 2000, describes activities and accomplishments from January 2020 through December 2021.

ADDRESSES: The report is available at https://ntp.niehs.nih.gov/go/2021iccvamreport.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Acting Director, NICEATM, Division of Translational Toxicology, NIEHS, P.O. Box 12233, K2–17, Research Triangle Park, NC 27709. Phone: 984–287–3150, Email: nicole.kleinstreuer@nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2032, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background:

The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences (NIEHS) under NICEATM. ICCVAM's mission is to facilitate development, validation, and regulatory acceptance of new and revised regulatory test methods that reduce, refine, or replace the use of animals in testing while maintaining and promoting scientific quality and the protection of human health, animal health, and the environment.

A provision of the ICCVAM Authorization Act states that ICCVAM shall prepare "reports to be made available to the public on its progress under this Act." The eleventh progress report describing ICCVAM activities and accomplishments from January 2020 through December 2021 is now available.

Summary of Report Contents: Key ICCVAM, ICCVAM agency, and NICEATM accomplishments summarized in the report include:

- Publication by the Organisation for Economic Co-operation and Development of Guideline 497, Defined Approaches on Skin Sensitisation, the first internationally harmonized guideline to describe a non-animal approach that can be used to replace an animal test to identify skin sensitizers. Guideline 497 was drafted and sponsored by ICCVAM agency scientists and international partners.
- Recommendations in March 2021 by the ICCVAM Metrics Workgroup on federal agency progress in promoting alternative toxicological methods. The workgroup recommended each agency develop its own metrics relevant and practical to their own situation.
- Establishment of the Workgroup on Microphysiological Systems for COVID Research, an international collaborative workgroup to coordinate use of

microphysiological systems to reduce animal use in COVID-19 studies and future emerging infectious diseases. A key accomplishment of the workgroup was the establishment of a COVID-19 disease portal in an existing microphysiological systems database.

- Further development of the Collaborative Acute Toxicity Modeling Suite (CATMoS), an online resource for in silico screening of organic chemicals for acute oral toxicity. During 2020 and 2021, the utility of CATMoS for predicting acute oral toxicity in research and regulatory contexts was explored in projects conducted by ICCVAM agencies, including the U.S. Department of Defense and the U.S. Environmental Protection Agency.
- Updates of the Integrated Chemical Environment Search tool during 2020 and 2021 to enable search results to be sent to query other data resources. Updates also allowed users to explore similarities among chemicals, find information on chemical use categories, search for structurally similar chemicals, and view and interact with concentration-response curves from curated high-throughput screening data.

Availability of Report: The report is available at https://ntp.niehs.nih.gov/go/2021iccvamreport. Links to this report and all past ICCVAM annual and biennial reports are available at http://ntp.niehs.nih.gov/go/iccvam-bien.

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 17 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability. ICCVAM also promotes the scientific validation and regulatory acceptance of testing methods that more

accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. Additional information about ICCVAM can be found at http://ntp.niehs.nih.gov/go/iccvam.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative testing approaches for validation studies and technical evaluations. Additional information about NICEATM can be found at http://ntp.niehs.nih.gov/go/niceatm.

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